

§ 900.20

standard whenever the agency determines that this action is necessary to protect the human health or otherwise is justified by § 900.12. Such action will become effective on the date specified in the written notice of the action sent to the applicant, except that it will become effective immediately upon notification of the applicant when FDA determines that such action is necessary to prevent an imminent health hazard.

[62 FR 55976, Oct. 28, 1997; 62 FR 60614, Nov. 10, 1997, as amended at 75 FR 20916, Apr. 22, 2010]

Subpart C—States as Certifiers

SOURCE: 67 FR 5467, Feb. 6, 2002, unless otherwise noted.

§ 900.20 Scope.

The regulations set forth in this part implement the Mammography Quality Standards Act (MQSA) (42 U.S.C. 263b). Subpart C of this part establishes procedures whereby a State can apply to become a FDA-approved certification agency to certify facilities within the State to perform mammography services. Subpart C of this part further establishes requirements and standards for State certification agencies to ensure that all mammography facilities under their jurisdiction are adequately and consistently evaluated for compliance with quality standards at least as stringent as the national quality standards established by FDA.

§ 900.21 Application for approval as a certification agency.

(a) *Eligibility.* State agencies may apply for approval as a certification agency if they have standards at least as stringent as those of § 900.12, qualified personnel, adequate resources to carry out the States as Certifiers' responsibilities, and the authority to enter into a legal agreement with FDA to accept these responsibilities.

(b) *Application for approval.* (1) An applicant seeking FDA approval as a certification agency shall inform the Food and Drug Administration, Center for Devices and Radiological Health, Director, Division of Mammography Quality and Radiation Programs, Attn: States as Certifiers Coordinator, 10903 New Hampshire Ave., Bldg. 66, rm. 4521,

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Silver Spring, MD 20993–0002, in writing, of its desire to be approved as a certification agency.

(2) Following receipt of the written request, FDA will provide the applicant with additional information to aid in the submission of an application for approval as a certification agency.

(3) The applicant shall furnish to FDA, at the address in paragraph (b)(1) of this section, three copies of an application containing the following information, materials, and supporting documentation:

(i) Name, address, and phone number of the applicant;

(ii) Detailed description of the mammography quality standards the applicant will require facilities to meet and, for those standards different from FDA's quality standards, information substantiating that they are at least as stringent as FDA standards under § 900.12;

(iii) Detailed description of the applicant's review and decisionmaking process for facility certification, including:

(A) Policies and procedures for notifying facilities of certificate denials and expirations;

(B) Procedures for monitoring and enforcement of the correction of deficiencies by facilities;

(C) Policies and procedures for suspending or revoking a facility's certification;

(D) Policies and procedures that will ensure processing certificates within a timeframe approved by FDA;

(E) A description of the appeals process for facilities contesting adverse certification status decisions;

(F) Education, experience, and training requirements of the applicant's professional and supervisory staff;

(G) Description of the applicant's electronic data management and analysis system;

(H) Fee schedules;

(I) Statement of policies and procedures established to avoid conflict of interest;

(J) Description of the applicant's mechanism for handling facility inquiries and complaints;

(K) Description of a plan to ensure that certified mammography facilities will be inspected according to MQSA (42 U.S.C. 263b) and procedures and